

(19)



Europäisches Patentamt

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(11)

EP 0 856 292 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:

05.08.1998 Bulletin 1998/32

(51) Int Cl. 6: A61B 17/39

(21) Application number: 98300479.7

(22) Date of filing: 23.01.1998

(84) Designated Contracting States:

AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC
NL PT SE

Designated Extension States:

AL LT LV MK RO SI

- Valencia, Aurelio
East Palo Alto, California 94304 (US)
- Li, Hong
Cupertino, California 95014 (US)
- Karrat, Joseph M.
Sunnyvale, California 94087 (US)

(30) Priority: 04.02.1997 US 794803

(71) Applicant: MEDTRONIC, INC.
Minneapolis, Minnesota 55432 (US)

(74) Representative: Bayliss, Geoffrey Cyril et al
BOULT WADE TENNANT,
27 Furnival Street
London EC4A 1PQ (GB)

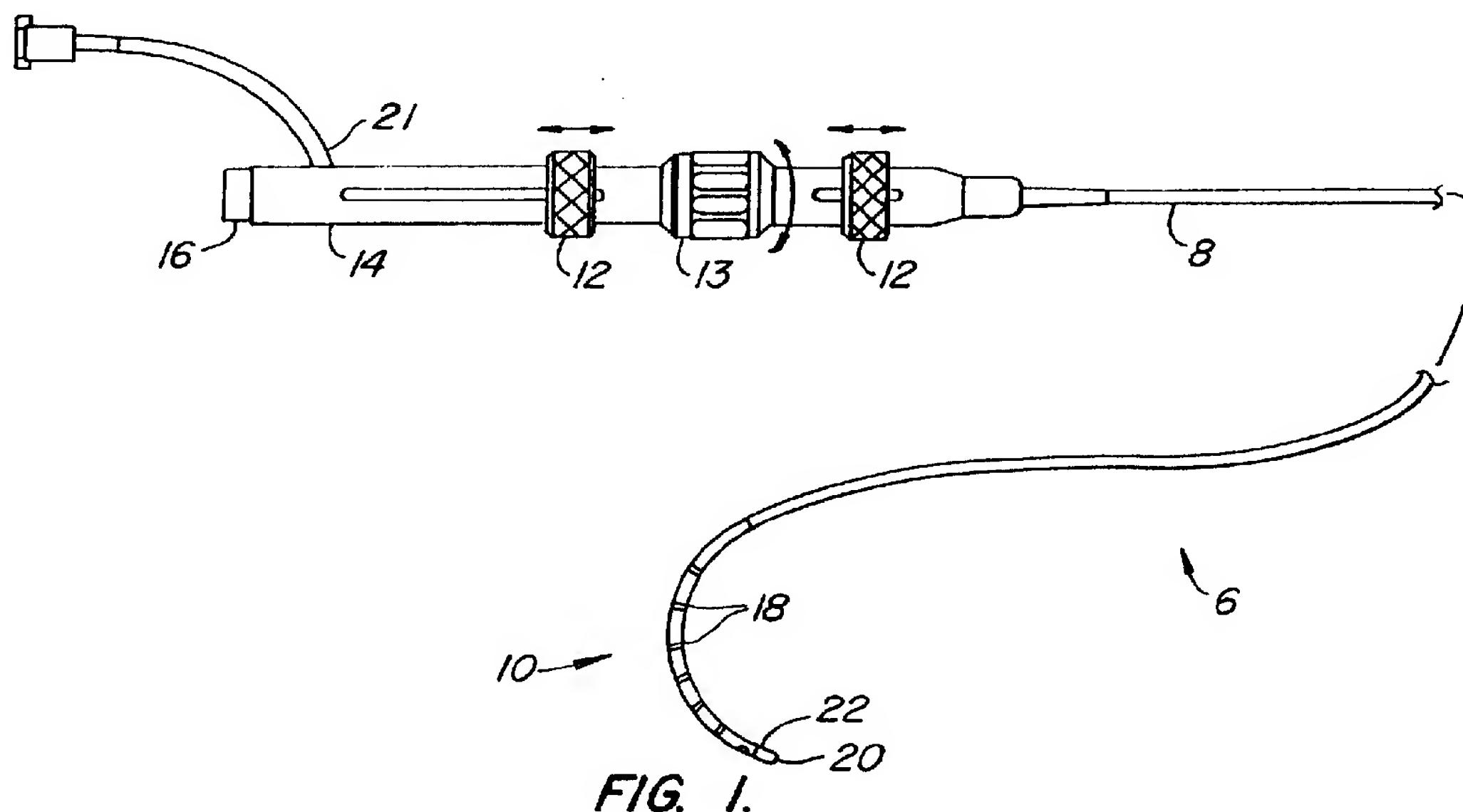
(72) Inventors:

- Maguire, Mark
San Jose, California 95125 (US)

(54) Fluid cooled ablation catheter and method for making

(57) A catheter assembly (2) includes a catheter shaft (6) having a tip portion (10) with a hollow interior (30) and a linear ablation electrode (18, 34, 36, 44, 58) spaced apart from the distal end (22) of the tip portion. The electrode has an inner surface (28) which is effectively fluidly exposed to the hollow interior so that a cooling fluid (32) passing through the interior contacts the inner surface so to effectively cool the electrode. The

electrode can include a series of band electrodes (18, 34) or one or more spiral electrodes (36, 44, 58). One method for making the tip portion involves mounting the electrode to a mandrel, filling the spaces between the edges (26) of the electrode with a polymer and then removing the resulting tubular structure from the mandrel. The cooling fluid can pass through a hollow spiral electrode (58) for enhanced cooling effectiveness.



EP 0 856 292 A1

Description

Catheter assemblies are often used to ablate surface tissue within a heart. The catheter assembly typically includes a handle and a catheter shaft extending from the handle, the catheter shaft having a tip portion. The tip portion typically includes a tip ablation electrode at the distal end and a linear ablation electrode along the tip portion spaced apart from the tip electrode. The linear ablation electrode is typically a series of circular band electrodes, one or more spiral electrodes or one or more braided electrodes. While it is desirable to ablate tissue at the target site, it is not desirable to overheat the tissue, or the blood in the vicinity of a target site, because blood can desiccate causing coagulum.

The present invention is directed to an ablation catheter assembly in which one or more linear ablation electrodes extending along the catheter shaft are cooled by permitting cooling fluid, typically saline, to effectively directly contact the inner surface of the linear ablation electrodes.

The fluid cooled ablation catheter assembly includes a catheter shaft having a tip portion with a hollow interior, defining a fluid passage, and a distal end. The tip portion also has a linear ablation electrode spaced apart from the distal end. The linear electrode has an inner surface which is effectively fluidly exposed to the fluid passage of the tip portion so that a cooling fluid passing through the fluid passage effectively directly contacts the inner surface so to efficiently cool the linear electrode. A primary advantage of the invention is that it permits electrodes at other than the tip of the catheter to be efficiently cooled using a cooling fluid.

The inner surface of the linear electrode is effectively fluidly exposed to the cooling fluid in two basic ways. First, the inner surface of the linear electrode can be an uncoated, bare surface so the cooling fluid wets the bare surface. This can occur by having all or part of the inner surface directly or indirectly fluidly coupled to the fluid passage of the tip portion. It can also occur if all or part of the inner surface of the linear electrode is covered by a porous material which allows the cooling fluid to contact the bare inner surface of the linear electrode. Second, the inner surface can be covered by a material which prevents direct contact by the cooling fluid with a bare inner surface of the linear electrode; in this event the material must be such to not impede heat transfer between the inner surface of the linear electrode and the cooling fluid to any significant extent. Such a material would preferably have a thermal conductivity adequate to allow the cooling fluid to maintain an electrode temperature between about body temperature (37° C), or slightly below, and 100° C, but more preferably between about 37° C and 70° C to reduce the risk of blood coagulation. Such a covering material may be desired or necessary to ensure the columnar integrity of the catheter shaft is maintained even though a less-than-optimal bond is typically created between the metal

electrode and the shaft. For example, a thin layer of PTFE, polyamide or PET, such as .013 mm - .051mm (.0005"-.002") thick, could be used to cover the inner surface of the linear electrode and catheter shaft and not significantly impede heat transfer between the cooling fluid and the linear electrode. Although these materials may not be good heat conductors, the thinness of the layer in this example keeps its thermal insulation properties to a reasonably low value. Therefore, the cooling fluid is considered to effectively directly contact the inner surface of the linear ablation electrode when the heat transfer from the linear electrode to the cooling fluid is such that the electrode temperature is maintained at the temperatures discussed above.

One method for making the tip portion of the catheter shaft involves mounting the electrodes to a mandrel and then filling the spaces between the edges of the electrodes with a polymer. Other assembly and construction methods can also be used.

The cooling fluid can be directed out of the catheter at the distal end of the tip portion. Cooling fluid can also be directed out of the catheter (into the bloodstream) at locations other than the distal end. For example, exit holes for fluid egress can be located on or between individual ablation electrodes.

Alternatively, the cooling fluid can be partly or totally recirculated, that is directed back up through the catheter shaft after having passed and cooled the linear electrode. Therefore, the amount of cooling is not limited by the amount of the cooling fluid, such as saline, that can be properly or safely injected into the patient. This recirculation ability is therefore useful when it is desirable to limit or prevent injection of fluid into the patient.

Other features and advantages of the invention will appear from the following description in which the preferred embodiments have been set forth in detail in conjunction with the accompanying drawings.

Fig. 1 is a simplified overall view of a catheter assembly made according to the invention;
 Fig. 2 is an enlarged, simplified cross-sectional view of a section of the tip portion of the catheter assembly of Fig. 1 using a series of circumferential band electrodes along the tip portion, the band electrodes spaced apart from the distal end of the tip portion;
 Fig. 3 is a view similar to Fig. 2 but using semicircular electrodes;
 Fig. 4 is a view similar to Fig. 2 but using a spiral electrode;
 Fig. 5 shows a tip portion including an outer tubular member similar to the tip portion of Fig. 4 and an inner tubular member with a series of holes providing fluid access to the inside surface of the spiral electrode;
 Fig. 6 shows a structure similar to that of Fig. 5 but using the band electrodes of Fig. 2 and having complete circumferential gaps in the inner tubular member exposing the entire inner surfaces of the band

electrodes;

Fig. 7 illustrates an alternative tip portion showing two spiral electrodes having circular cross-sectional shapes embedded within an outer tubular member, the inside surface of the electrodes and the outer tubular member being covered by a porous liner; Fig. 7A is a longitudinal cross-sectional view of the tip portion of Fig. 7;

Fig. 7B is a radial cross-sectional view taken along line 7B-7B of Fig. 7 showing an inner fluid flow passage defined within the interior of the tip portion and a fluid impermeable tube also within the interior and through which various electrical wires and manipulator elements can pass, the tube not being shown in Fig. 7A for ease of illustration;

Fig. 7C is an enlarged view of a portion of Fig. 7A illustrating the exposure of the inside surface of the spiral electrode to the porous liner;

Fig. 8 is a view similar to Fig. 7B but showing a porous bi-lumen extrusion within the interior of the tip portion;

Fig. 9 is a longitudinal cross-sectional view of an alternative tip portion made according to the invention;

Fig. 9A is an enlarged view of a portion of the tip portion of Fig. 9 showing the entrance to the fluid passage;

Fig. 9B illustrates the tip portion of Fig. 9 during fluid flow through the fluid passage;

Fig. 9C is an enlarged view of a portion of the tip portion of Fig. 9B illustrating passage of the cooling fluid into the fluid passage;

Fig. 10 is a view similar to Fig. 9 of an alternative embodiment in which several exits from the fluid passage are positioned along the length of the tip portion;

Fig. 11 is an overall view of a further embodiment of a catheter assembly using hollow spiral electrodes;

Fig. 11A is an enlarged view of a part of a tip portion of the catheter assembly of Fig. 11;

Fig. 11B is a longitudinal cross-sectional view of the tip portion of Fig. 11A illustrating the flow of cooling fluid through the spiral electrodes;

Fig. 11C is a cross-sectional view taken along line 11C-11C of Fig. 11B; and

Fig. 12 is a partial side view of the tip portion of a still further embodiment of the invention.

Fig. 1 illustrates a catheter assembly 2 comprising a handle 4 and a catheter shaft 6 extending from the handle. Catheter shaft 6 includes a main portion 8 and tip portion 10. Tip portion 10 is, as is standard, relatively flexible to be maneuverable and placeable in different configurations by one or more manipulators 12, 13 mounted to body 14 of handle 4. Handle 4 includes an electrical connector 16 to permit electrical connection with a set of electrodes 18 carried by tip portion 10. Elec-

trodes 18 are ablation-capable electrodes. Electrodes 18 are used to create linear lesions and are sometimes collectively referred to herein as a linear ablation electrode or a linear electrode. These various components 5 discussed above with reference to Fig. 1 are generally conventional. See, for example, U.S. Patent No. 5,487,757, entitled "Multicurved Deflectable Catheter" and U.S. Patent Application No. 08/613,298, filed March 11, 1996, entitled "Method and Apparatus for RF Ablation." Handle 4 also has a fluid port 21 which permits saline, or another cooling fluid, to be directed through catheter shaft 6 to cool electrodes 18 as discussed below.

Figs. 2-6 are simplified views and do not show various elements, such as radial deflection manipulator wires, lateral deflection core wires, thermocouple wires, electrical power wires, etc., for ease of illustration.

Fig. 2 illustrates an enlarged simplified sectional view of a section of tip portion 10 including two band electrodes 18. Tip portion 10 is seen to include alternating lengths of band electrodes 18 and polymer sections 24 made of polyurethane or other suitable materials. Electrodes 18 of the embodiment of Fig. 2 may have the smooth sides indicated only if a sufficiently strong bond 20 can be created between metal electrodes 18 and polymer sections 24. It may, however, be necessary to provide mechanical interlocking features which enhance the connection between electrodes 18 and sections 24.

Band electrodes 18 are typically made of platinum-30 iridium or stainless steel. In this way the inside surfaces 28 of band electrodes 18 are fully exposed to the interior 30 of tip portion 10. The provision of cooling fluid 32, typically saline, along interior 30 allows the cooling fluid to directly contact inside surface 28 of band electrodes 35 18 thus efficiently cooling the band electrodes during ablation procedures. Cooling fluid 32 passes through interior 30 and out an exit opening 33 adjacent to tip portion 10.

Fig. 3 illustrates an alternative embodiment of the 40 invention similar to Fig. 2. However, instead of circumferential band electrodes 18, semicircular band electrodes 34 are used as the linear ablation electrode with tip portion 10a. This is to allow more cross-sectional area to be comprised of catheter shaft material to maintain adequate structural support.

Fig. 4 is an embodiment similar to Fig. 2 and shows a tip portion 10b using one or more spiral electrodes 36 as the linear ablation electrode.

Fig. 5 illustrates a tip portion 10c comprising an outer tubular member 38 similar in construction to tip portion 10b and an inner tubular member 40. Inner tubular member 40 is made of a polymer material, such as polyurethane, silicone, PET or polyimide, and has a series of holes 42 therein. Holes 42 are positioned to be 50 aligned with the inner surface 28 of spiral electrodes 36. In this way the interior 30c of tip portion 10c is in fluid communication with the inside surface 28 of spiral electrodes 36 to permit cooling saline 32 to contact inner

surface 28 of spiral electrodes 36.

Inner tubular member 40 could be replaced by a braided tubular structure to provide uniform shaft support for the electrodes; such a braided or other woven tubular structure would have numerous and substantial openings so the cooling fluid can contact the inside surfaces of the electrodes.

Fig. 6 illustrates an alternative to the embodiment shown in Fig. 5. In Fig. 6 tip portion 10d includes an outer tubular member 38d similar to tip portion 10 of Fig. 2 and an inner tubular member 40d similar to inner tubular member 40 of Fig. 5. However, inner tubular member 40d has circumferentially extending cutouts 44 aligned with each band electrode 18 to permit all or a substantial part of inside surface 28 to be contacted by cooling saline 32, as opposed to the situation of Fig. 5 in which only a portion of the inside surface 28 is directly exposed to the cooling saline 32.

Tip portion 10 can be made by mounting or forming band electrodes 18 on a mandrel, and then filling the region between the lateral edges 26 of the band electrodes with a suitable polymer to create the tubular structure illustrated in Fig. 2. After curing, tip portion 10 is mounted to the distal-most polymer section 24 in a conventional manner, typically through the use of an adhesive or heat welding.

The construction of tip portion 10c could proceed generally as follows. A tubular member 40 is formed with holes 42 and then mounted on a mandrel. Spiral electrode 36 is then wound about inner tubular member 40 covering holes 42. A suitable thermoplastic polymer or thermoset material, such as silicone, is then introduced between opposed lateral sides 26b of spiral electrode 36 so to fill the space between the sides. When sufficiently cured, the structure is then removed from the mandrel and a tip electrode 20 can be mounted in a conventional fashion.

The above embodiments have been described on the basis that tip portion 10 has an exit opening 33 adjacent tip portion 10; see Fig. 1. This type of fluid flow, in which the cooling fluid, typically saline, exit adjacent or through the tip portion, is shown in U.S. Patent No. 5,348,554, entitled "Catheter for RF Ablation with Cooled Electrode", and U.S. Patent No. 5,462,521, entitled "Fluid Cooled and Perfused Tip for a Catheter." U. S. Patent No. 5,348,554 also illustrates a catheter having a cooling fluid return passageway so that cooling fluid, after reaching the distal end of the tip section of the catheter, can be returned to the source so that the cooling fluid does not flow into the body but rather recirculates. Parallel conduit, recirculating systems can be used with the present invention. A system could also be devised in which part of the cooling fluid was directed out of the tip portion of the catheter shaft and part recirculated; fluid could also be directed out of the catheter at or between each electrode.

In use, tip portion 10 is located at the appropriate target site using manipulators 12 on handle 4. When in

position, appropriate energy is applied to the ablation electrodes, such as band electrodes 18 or spiral electrodes 36, to ablate the tissue. During ablation, coolant, typically saline 32, is passed through port 21, through 5 catheter shaft 6 and into interior 30 of tip portion 10 where the saline comes into direct physical contact with inner surface 28 of the ablation electrodes so to cool the ablation electrodes. This helps to reduce overheating in the vicinity of ablation electrodes 18, 36 thus helping to 10 eliminate undesirable consequences of overheating, such as the excessive coagulation of blood and the unintended destruction of healthy tissue adjacent to the target site. The efficient cooling of the linear ablation electrode permits longer lesions to be created by permitting higher RF powers without resulting in excessive 15 electrode heating. The lesions will be deeper into the tissue and will tend to flow into one another, that is join up, to create a linear lesion when using spaced-apart band or spiral electrodes. Cooling fluid, such as saline 20 32, can also be permitted to pass out of tip portion, such as through opening 33 adjacent to tip 20, or through other openings formed, for example, adjacent or through each band electrode 18; alternatively, some or all of the 25 cooling fluid could be caused to recirculate and not be expulsed from tip portion 10.

It is known to cool a tip electrode and apply the cooled tip electrode to a target site while monitoring the heart to see if cooling the target site has a positive affect on arrhythmia; if it does then the tissue at the target site 30 is ablated. The invention can also be used to test for the expected effectiveness of creating a linear lesion at a target site. To do so tip portion is positioned so the linear ablation electrode is at the target site and the linear electrode is cooled by the cooling fluid to chill the tissue sufficiently to create what is sometimes called a test lesion. 35 If chilling the tissue at the target site affects arrhythmia in a positive way, energy is supplied to the linear ablation electrode to ablate the tissue and create a linear lesion at the target site.

40 Figs. 7-7C illustrate alternative tip portion 10e comprising a plurality of spiral electrodes 44 having circular cross-sectional shapes. Electrodes 44 are embedded within and carried by outer tubular member 38e. The inside surfaces 28e, see Fig. 7C, of spiral electrodes 44 and the inside surface 46 of outer tubular member 38e are covered by a porous inner tubular member 40e.

45 Porous inner tubular member 40e is preferably a silicone, polyolefin, or other suitable porous material about .025 mm - .25 mm (.001"-.010") thick, more preferably about .076 mm - .20 mm (.003"-.008") thick, to provide fluid access to the inner surface 28e of electrodes 44 while providing some structural support to tip portion 10e. Fig. 7B illustrates a liquid impervious tube 48 extending along the interior 30e of tip portion 10e. 50 Tube 48 is used to guide various wires and other components along tip portion 10e and keep those components from being exposed to cooling fluid 32. In the embodiment of Figs. 7-7C cooling fluid 32 exits tip portion 55

10e through an axial hole 49 formed in tip portion 10e. Alternatively, an additional tube, similar to tube 48, could be used to direct cooling fluid 32 in a reverse fluid flow along tip portion 10e.

Fig. 8 illustrates a cross-sectional view similar to that of Fig. 7B but using a porous bi-lumen extrusion as the inner tubular member 40f. Inner tubular member 40f divides interior 30f into a main region 50, through which cooling fluid 32 flows, and a supplemental region 52 housing tube 48, tube 48 serving the same purpose as in the embodiment of Figs. 7-7C. Extrusion 40f may be made of a suitable porous material such as polyethylene, polyolefin or silicone.

Figs. 9-9C illustrate a further embodiment of the invention in which a tip portion 10g has a radially expandable outer tubular member 38g. Member 38g includes a silicone layer 54 which dilates to define fluid passage 30g, see Fig. 9C, between silicone layer 54 and inner tubular member 40g. This dilation occurs when cooling fluid 32 is supplied at a sufficiently high pressure at the entrance 56 to fluid passage 30g to cause the cooling fluid to flow along the dilated passage 30g and exit tip portion 10g at exit openings 33g. Silicone layer 54 is sufficiently thin, such as .013 mm - .051 mm (.0005" to .002") thick, so that cooling fluid 32 need not actually contact the inside surfaces of electrodes 44 to effectively cool the electrodes. Alternatively, silicone layer 54 can be a porous silicone to provide actual direct contact of the cooling fluid with the inside surfaces of electrodes 44.

Fig. 10 illustrates a tip portion 10h similar to tip portion 10g but having a number of exits 33h along the tip portion. This can be useful because it not only causes convective cooling of the electrodes, but causes the cooling fluid to also directly cool or "bathe" the issue being ablated.

Figs. 11-11C illustrate a further embodiment of the invention in which a tip portion 10i has a plurality of tubular spiral electrodes 58. Electrodes 58 are preferably stainless steel hypotubes having an outside diameter of about .36 mm (.014") and an inside diameter of about .25 mm (.010"). Proximal end 60 of each tubular electrode 58 opens into region 50 defined within inner tubular member 40h and through which cooling fluid 32 flows. Cooling fluid flows into proximal end 60, through the interior of tubular spiral electrode 58 and out through the distal end 62 of the spiral electrode. In this embodiment the inside surface of spiral electrode 58 corresponds to inside surface 28 of the electrodes in the other embodiments and permits direct cooling contact of the cooling fluid with the electrode. Although in this embodiment each electrode 58 has a single entrance and a single exit, each spiral electrode could have one or more entrances and one or more exits. For example, distal ends 62 could be blocked and spiral electrodes 58 could have numerous small openings 64, see Fig. 12, through which cooling fluid could flow out of tip portion 10j. The sizes of the small openings could be chosen to ensure

generally equal or unequal flow rates through the openings.

Other modifications and variation can be made to the disclosed embodiments without departing from the subject of the invention as defined in the following claims. For example, the invention could be constructed to ablate other than cardiac tissue, such as the prostate, the uterus, cancer tumors, or coronary artery blockages (plaques). Temperature sensors may be used to measure the temperature at the tissue interface; to do so temperature sensors should be positioned to provide the most accurate temperature measurements, typically positioned spaced-apart from the fluid-cooled electrodes. To increase the ID/OD ratio for the hollow coil design of Figs. 7-12, the hollow coil could have a flattened, rather than circular, cross-sectional shape. This smaller profile electrode would allow a smaller shaft OD or a larger shaft ID for catheter shaft components, such as fluid lumen, manipulator wire(s), electrical wires, etc.

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Claims

1. An ablation catheter assembly comprising:
a handle;
a catheter shaft extending from the handle;
the catheter shaft comprising a tip portion with a fluid passage and a distal end;
the tip portion further comprising a linear ablation electrode spaced-apart from the distal end;
said electrode comprising outer and inner surfaces; and
said inner surface being effectively fluidly exposed to said fluid passage so that a cooling fluid passing through said fluid passage effectively directly contacts said inner surface to cool the electrode.
2. The catheter according to claim 1 wherein said electrode is a tubular electrode having a proximal end, fluidly coupled to the cooling fluid within said fluid passage, and a distal end.
3. The catheter according to claim 1 wherein said linear ablation electrode comprises a plurality of spaced-apart band electrodes, and wherein at least one of said band electrodes is a circular electrode, a semicircular electrode or a spiral electrode.
4. The catheter according to claim 1 wherein said catheter shaft comprises an outer tubular member carrying said electrode and an inner tubular member within said outer tubular member, said inner tubular member comprising fluid flow paths for the passage of the cooling fluid between the inner surface of the electrode and the fluid passage.

5. The catheter according to claim 4 wherein said inner tubular member comprises at least one of:
 a porous material defining said fluid flow paths;
 a woven tubular member; and
 a plurality of discrete openings defining said fluid flow paths.

6. The catheter according to claim 1 wherein at least portions of said inner surface of said electrodes are bare surfaces exposed directly to said fluid passage.

7. The catheter according to claim 1 further comprising a liquid permeable porous material covering said inner surface.

8. The catheter according to claim 1 wherein said tip portion comprises an outer tubular member defining said fluid passage and a tubular conduit within said outer tubular member, said tubular conduit made of a material which acts as a barrier to the cooling fluid.

9. The catheter according to claim 1 wherein said tip portion comprises inner and outer tubular members defining said fluid passage therebetween, said fluid passage comprising an entrance, at least one exit, and a pressure-sensitive portion which opens only when the fluid pressure at the entrance of said fluid passage exceeds a chosen level so the cooling fluid can pass along the fluid passage from the entrance to the exit.

10. An ablation catheter assembly comprising:
 a handle;
 a catheter shaft extending from the handle;
 the catheter shaft comprising a tip portion with a fluid passage and a distal end;
 the tip portion further comprising a tubular linear ablation electrode having a fluid entrance and a fluid exit and defining a fluid flow path therebetween; and
 said fluid entrance fluidly coupled to said fluid passage so that a fluid passing through said fluid passage can enter and flow through said electrode.

11. The catheter according to claims 1 or 10 wherein said fluid exit opens into a region external of said catheter shaft.

12. The catheter according to claims 2 or 10 wherein said tubular electrode is a spiral tubular electrode.

13. The catheter according to claim 10 wherein:
 said fluid passage has a cooling fluid entrance
 5 to provide a cooling fluid to said passage and into said tubular electrode;
 said tubular linear ablation electrode comprises a plurality of spaced-apart spiral electrodes;
 said tubular linear ablation electrode has a circular cross-sectional shape; and
 said tubular linear ablation electrode is spaced apart from the distal end.

14. The catheter according to claim 10 wherein said tubular linear ablation electrode comprises a plurality of said fluid exits.

15. A method for making the tip portion of an ablation-capable catheter shaft comprising the following steps:
 15 positioning an inner surface of an electrode against an outer surface of a mandrel, said electrode having circumferentially-extending edges;
 20 depositing a polymer onto the outer surface of the mandrel and in contact with the circumferentially-extending edges so to bond to said edges to create a tubular structure having a hollow interior; and
 25 removing said tubular structure from said mandrel, whereby said inner surface of said electrode is exposed to said hollow interior so that a cooling fluid passing through said interior contacts and cools the electrode.

16. A method for making the tip portion of an ablation-capable catheter shaft comprising the following steps:
 30 forming an inner tubular member having an interior, an outer surface, a radial wall thickness and at least one fluid passageway formed through said radial wall thickness, said fluid passageway positioned along an electrode path;
 35 positioning an inner surface of an electrode against an outer surface of the inner tubular member and along the electrode path so to cover said at least one passageway, said electrode having circumferentially-extending edges;
 40 depositing a polymer onto the outer surface of the inner tubular member and in contact with the circumferentially-extending edges so to bond to said edges and to said outer surface to create a modified tubular structure; and
 45 removing said modified tubular structure from said mandrel, whereby said inner surface of said electrode is exposed to said hollow interior through said at least one passageway so that a cooling fluid passing through said interior contacts and cools the electrode.

17. The method according to claims 15 or 16 wherein the positioning step comprises the step of selecting the electrode from a group comprising a spiral electrode and circumferential band electrodes.

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18. The method according to claim 16 wherein said forming step is carried out so that said fluid passageway comprises a series of spaced-apart fluid passageways.

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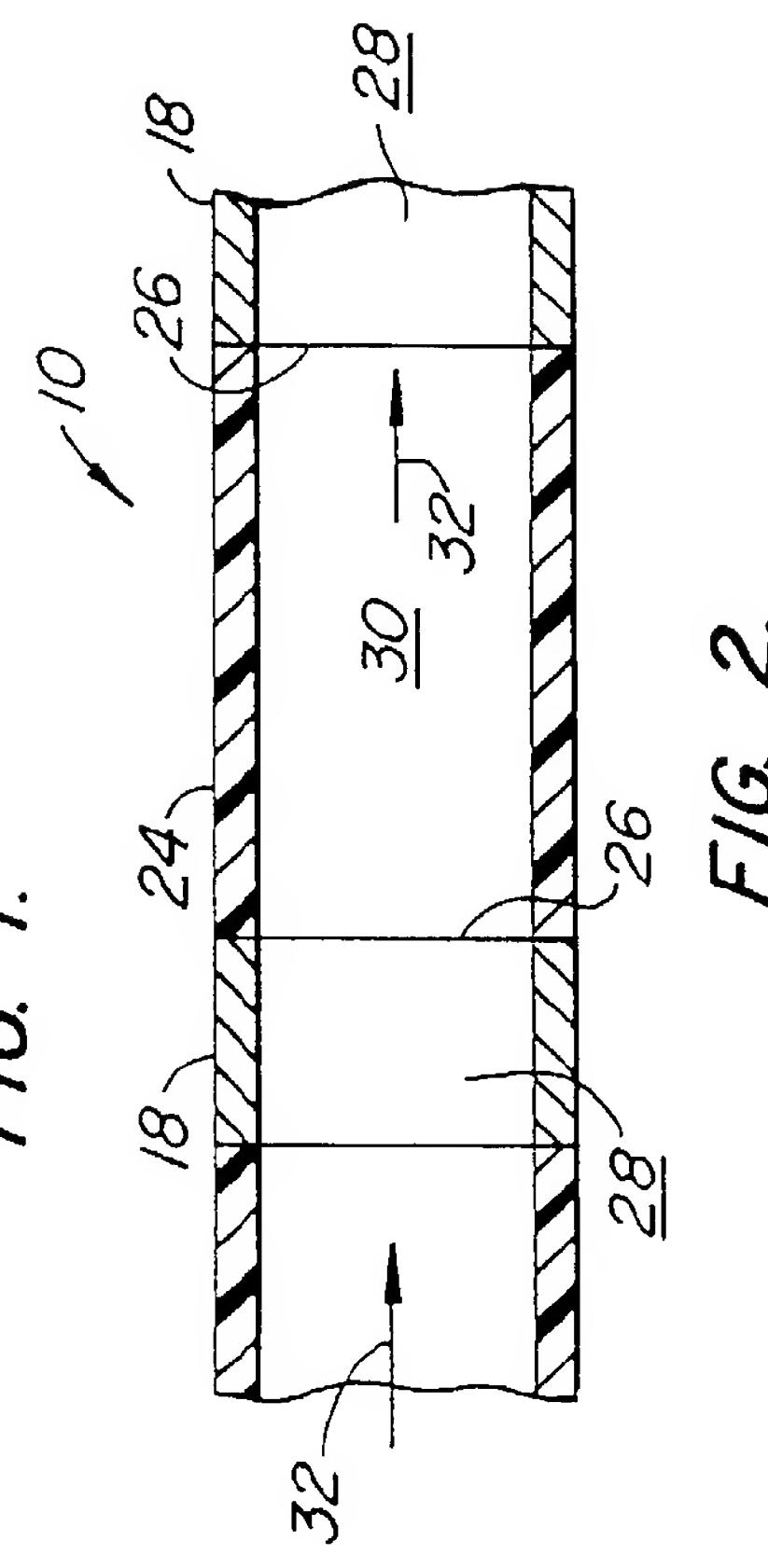
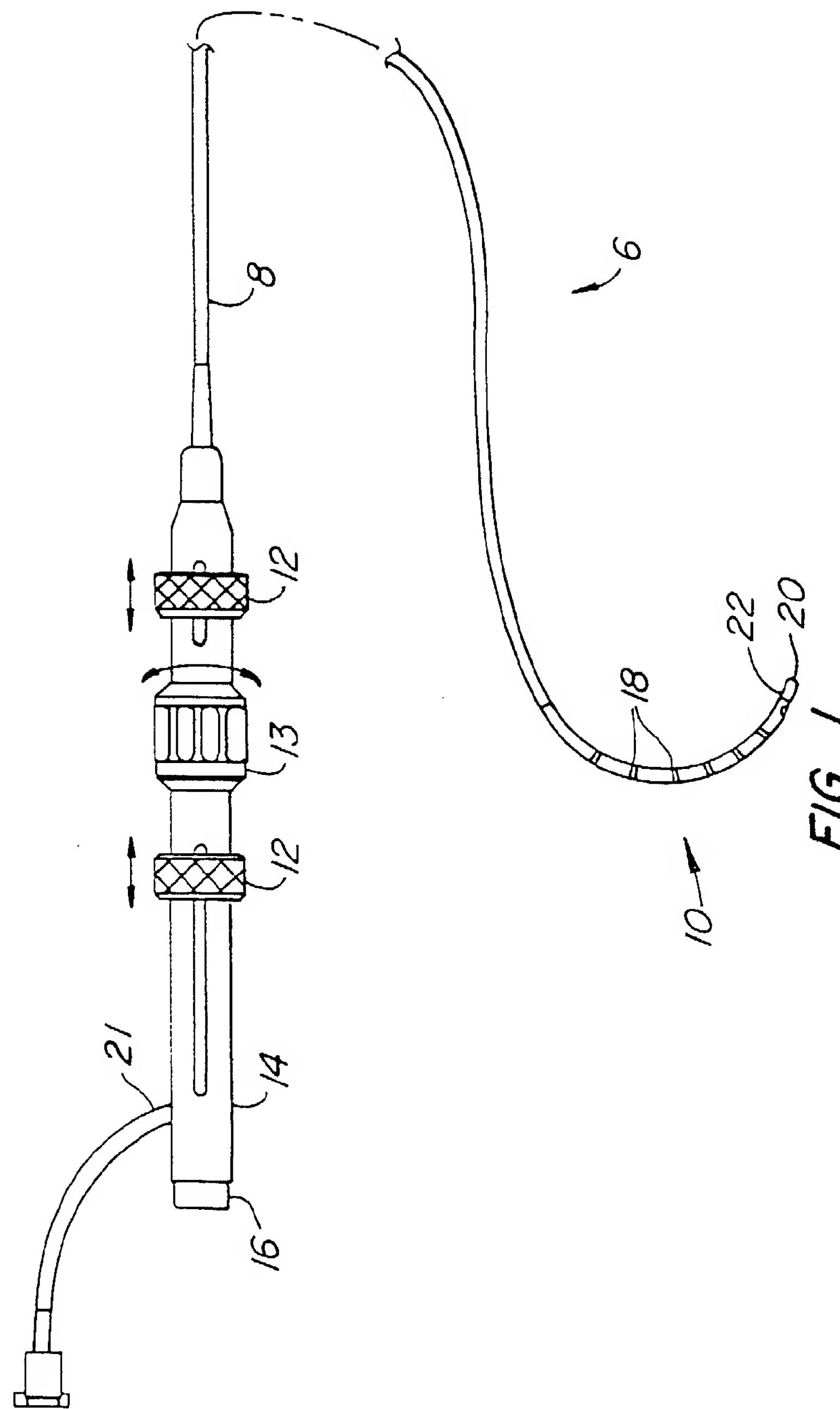
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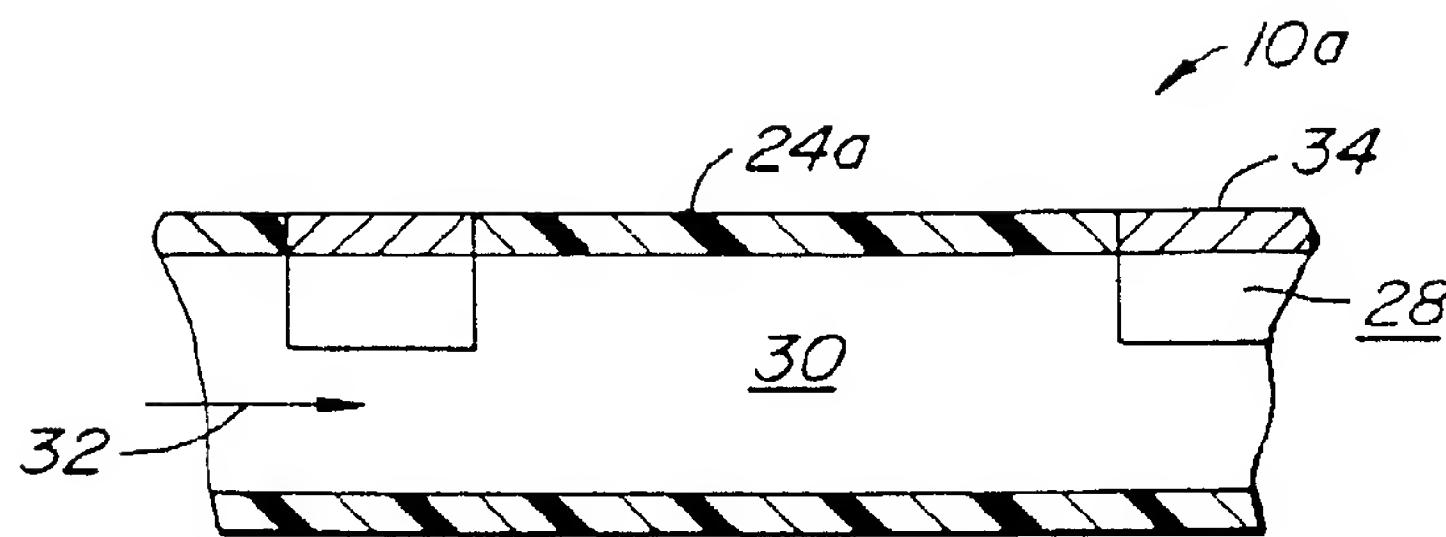


FIG. 3.

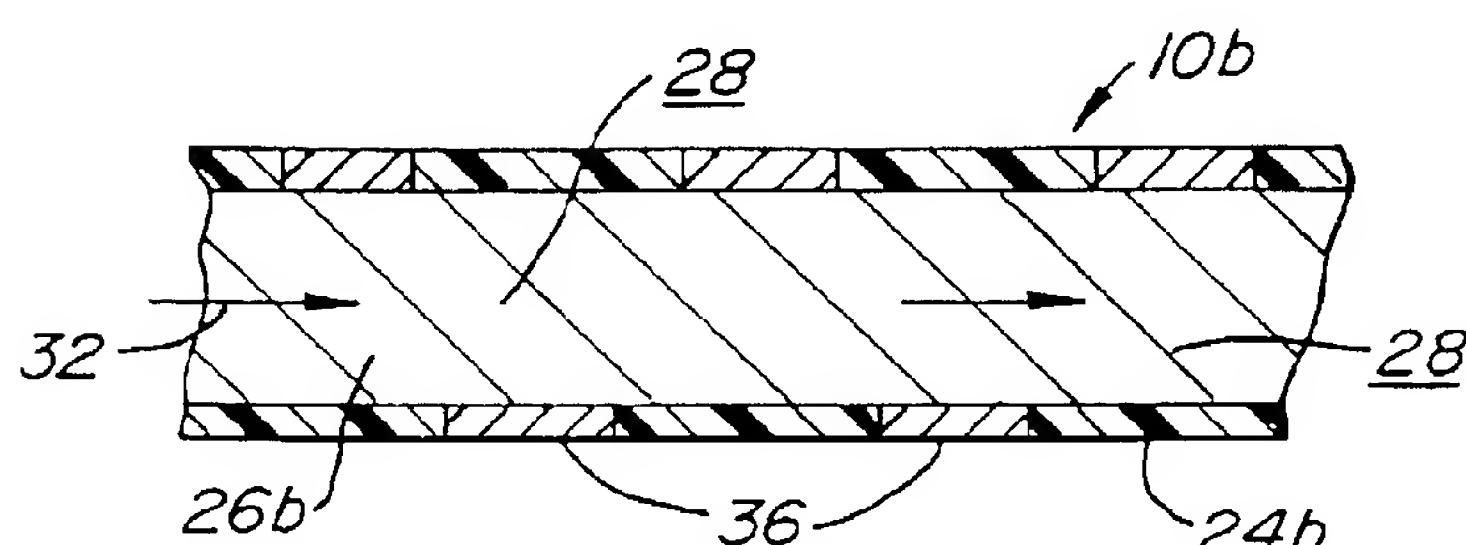


FIG. 4.

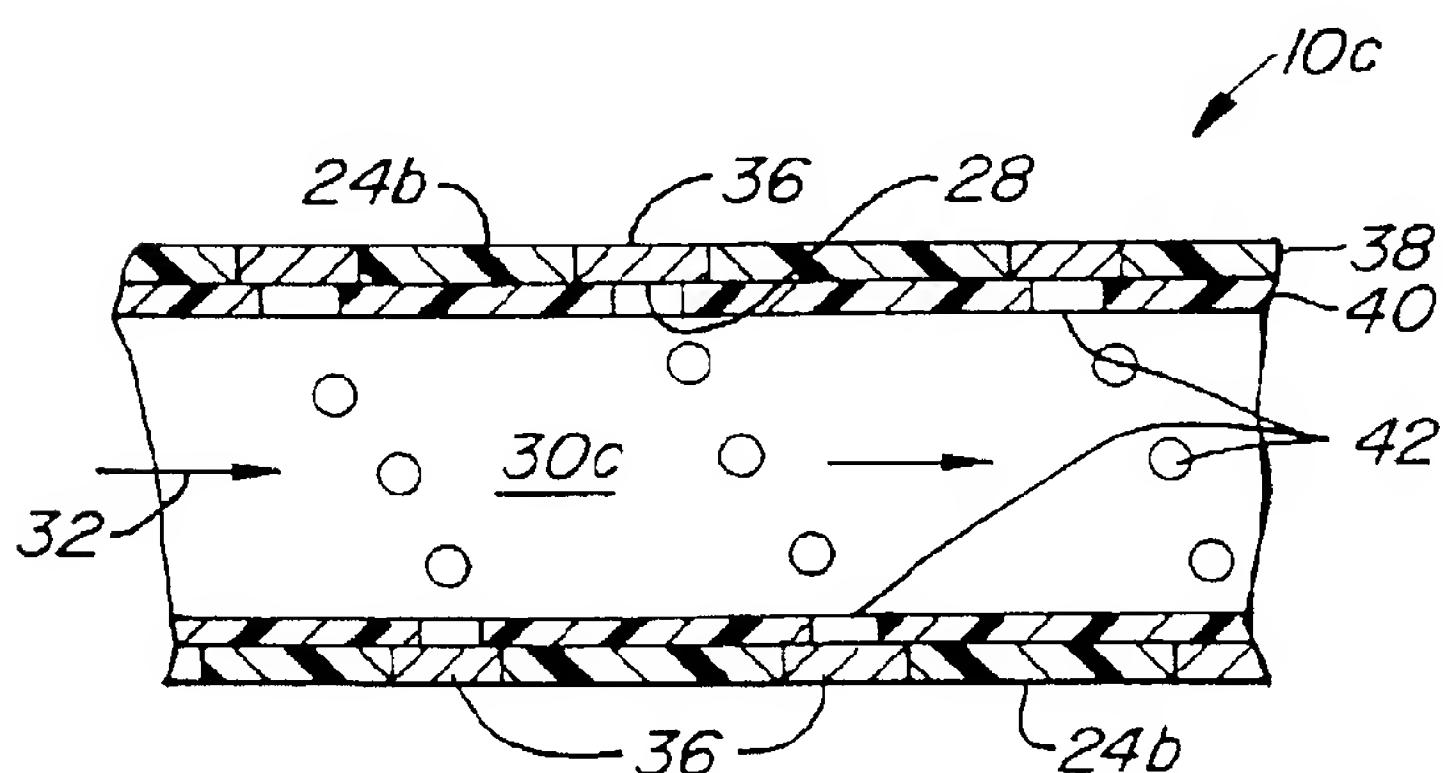


FIG. 5.

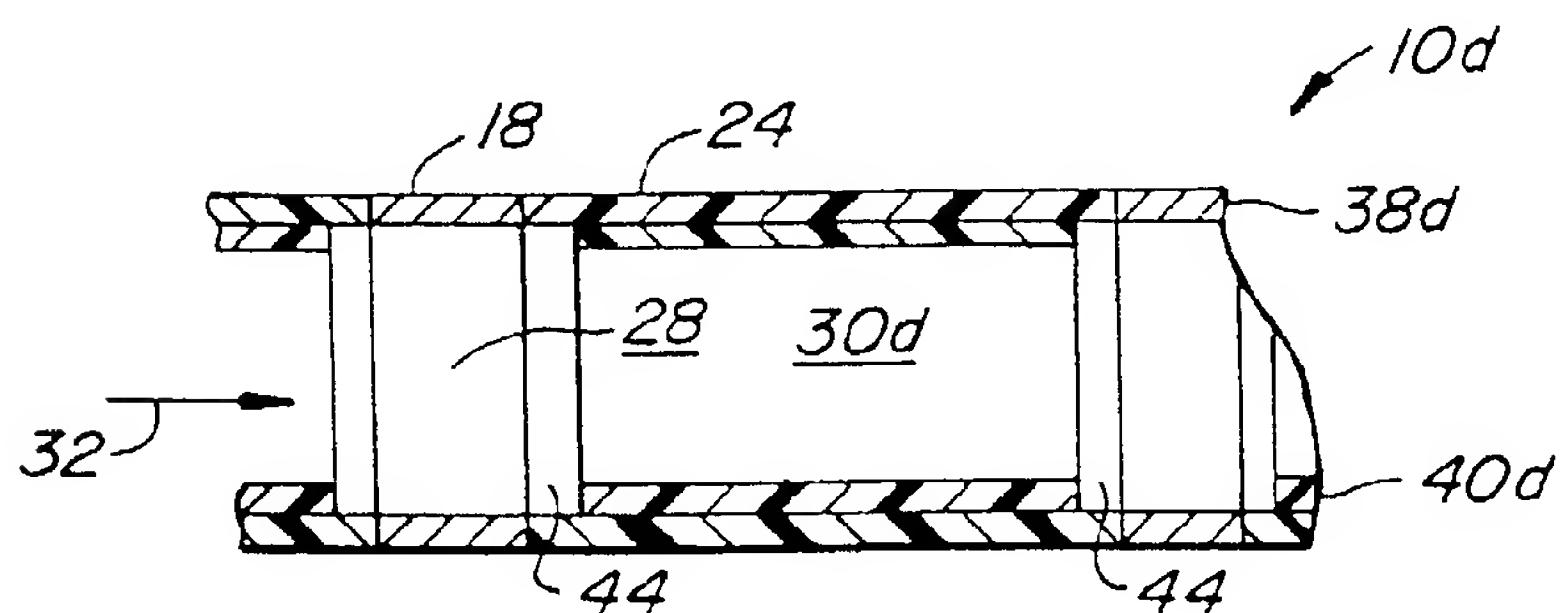


FIG. 6.

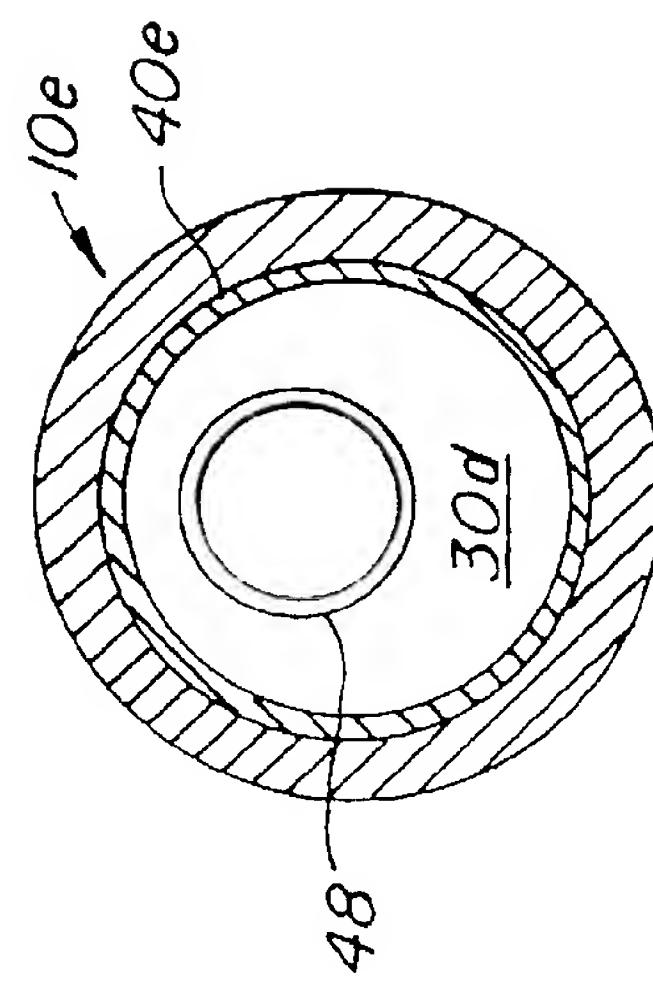
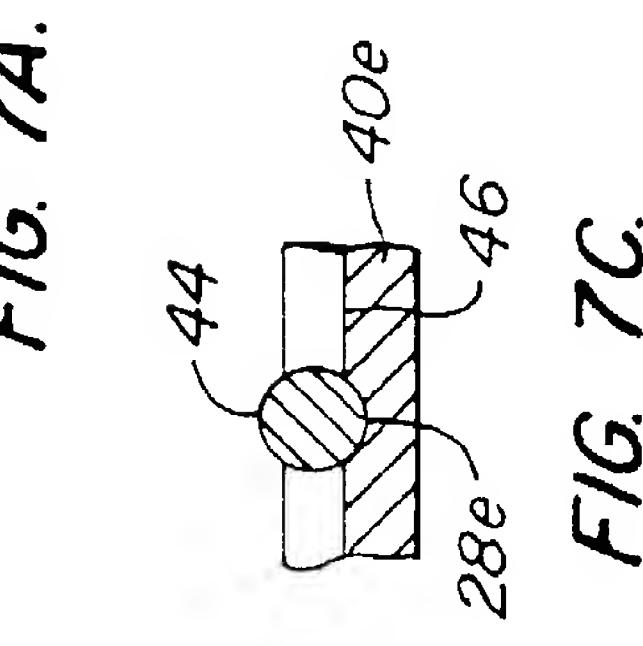
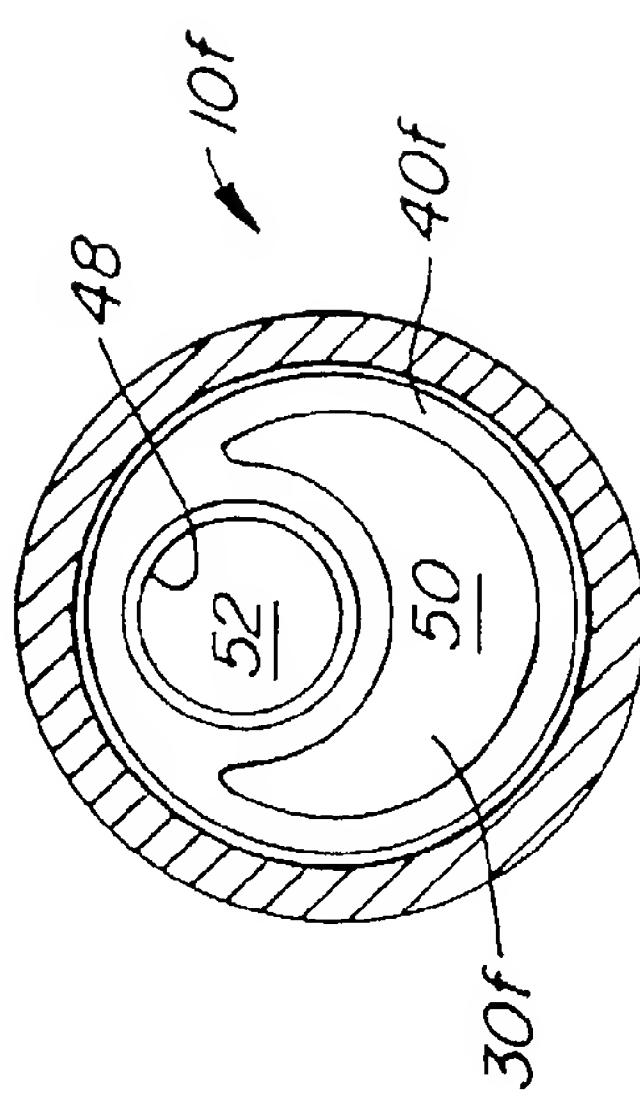
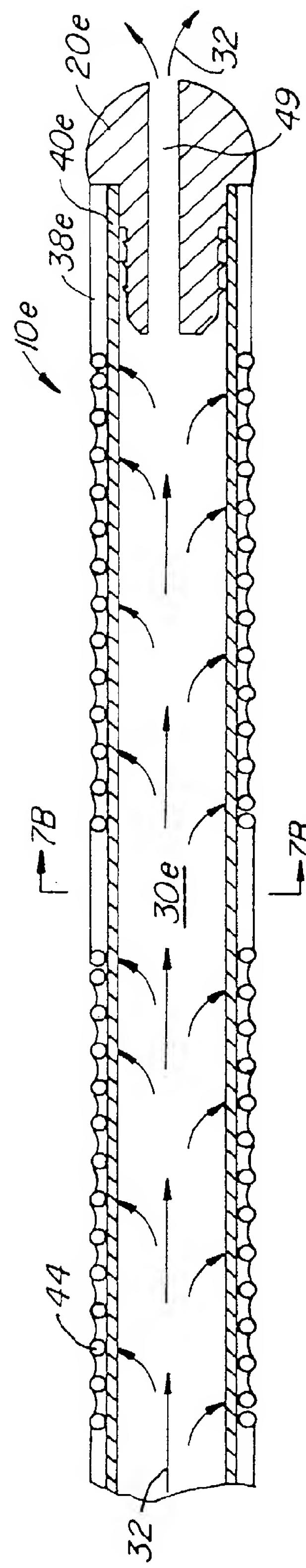
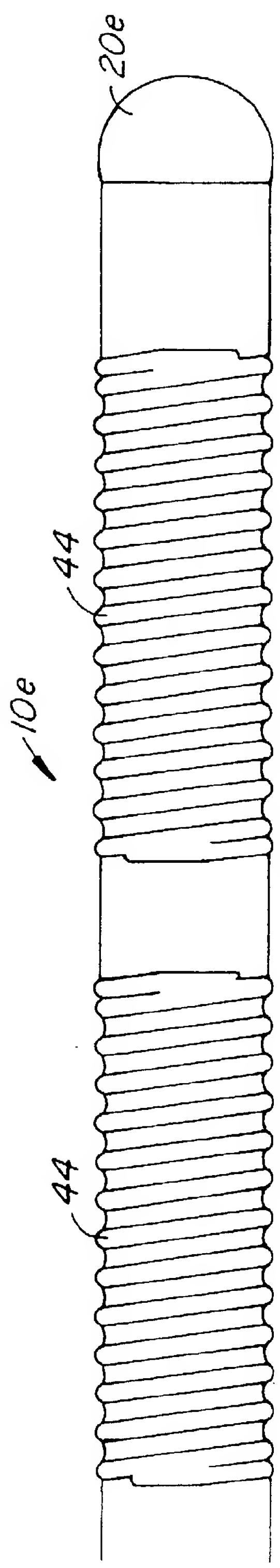


FIG. 8.

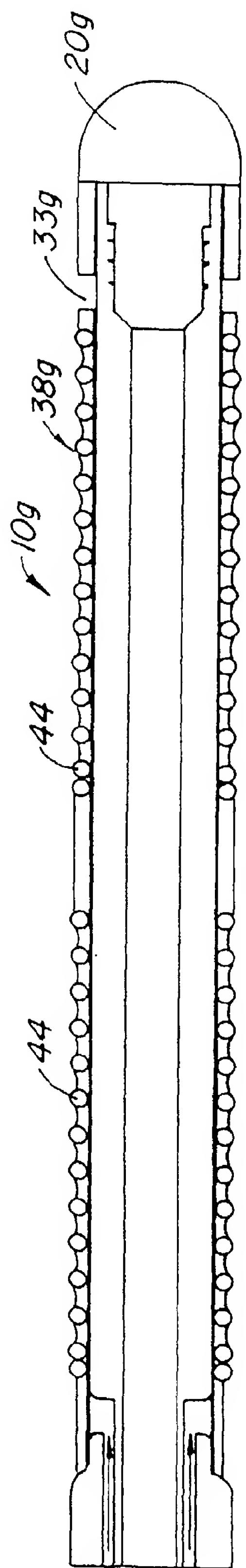


FIG. 9.

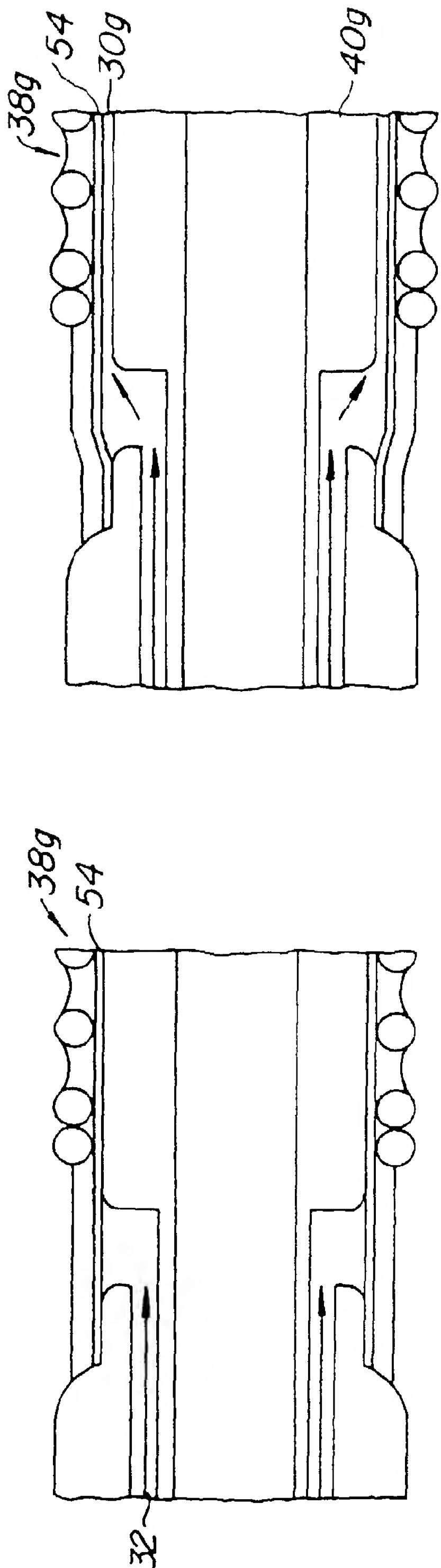


FIG. 9A.

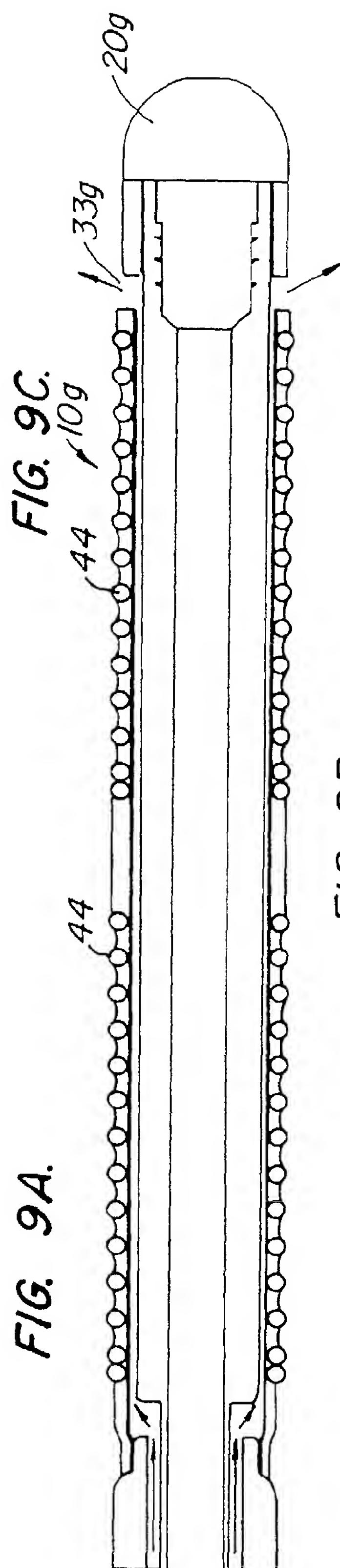


FIG. 9B.

FIG. 9C.

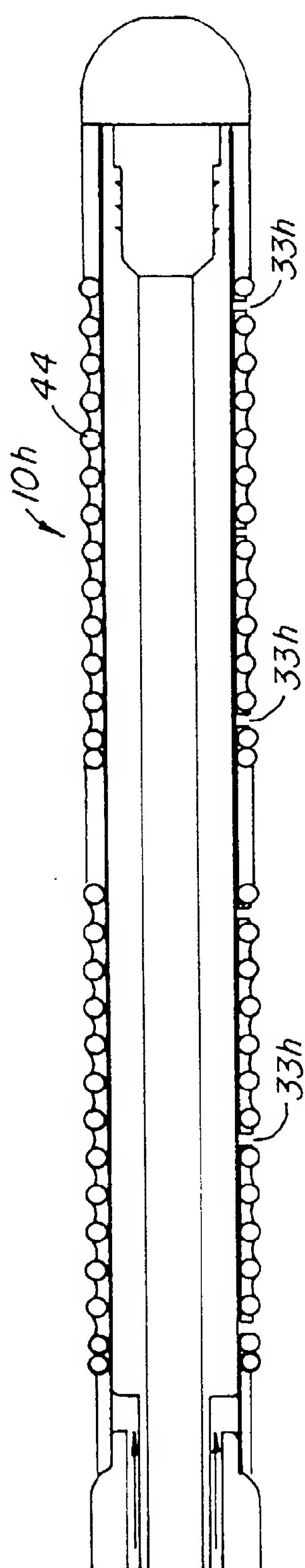


FIG. 10.

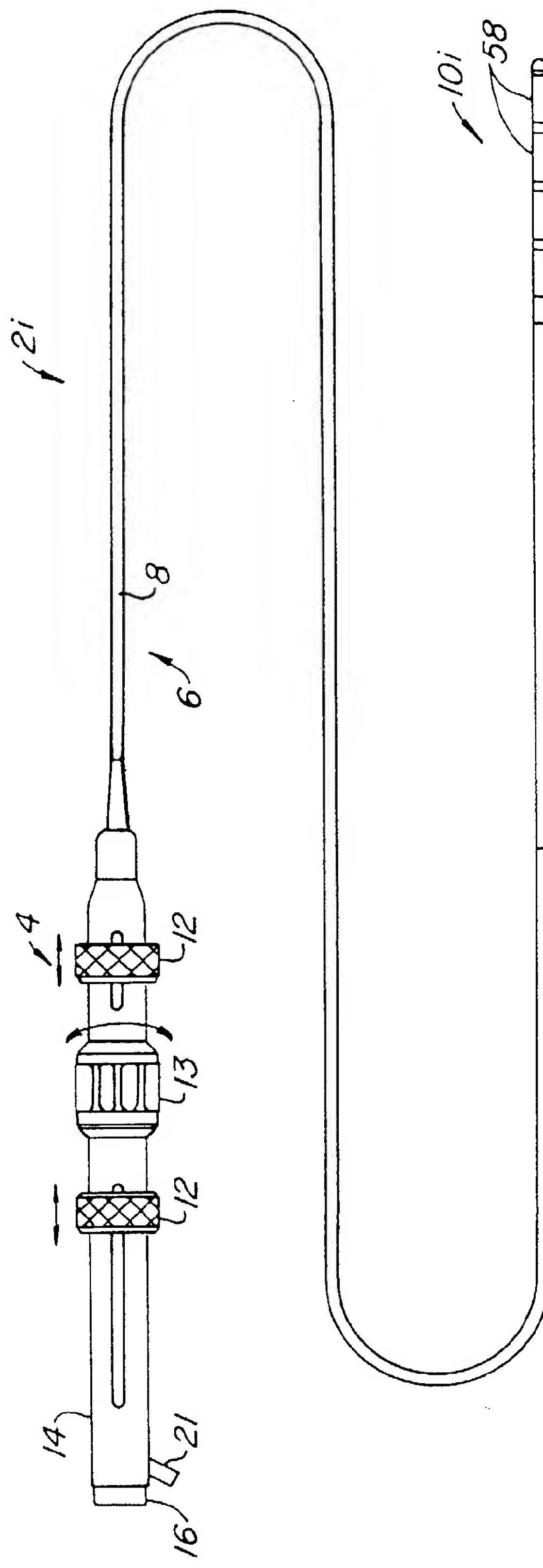
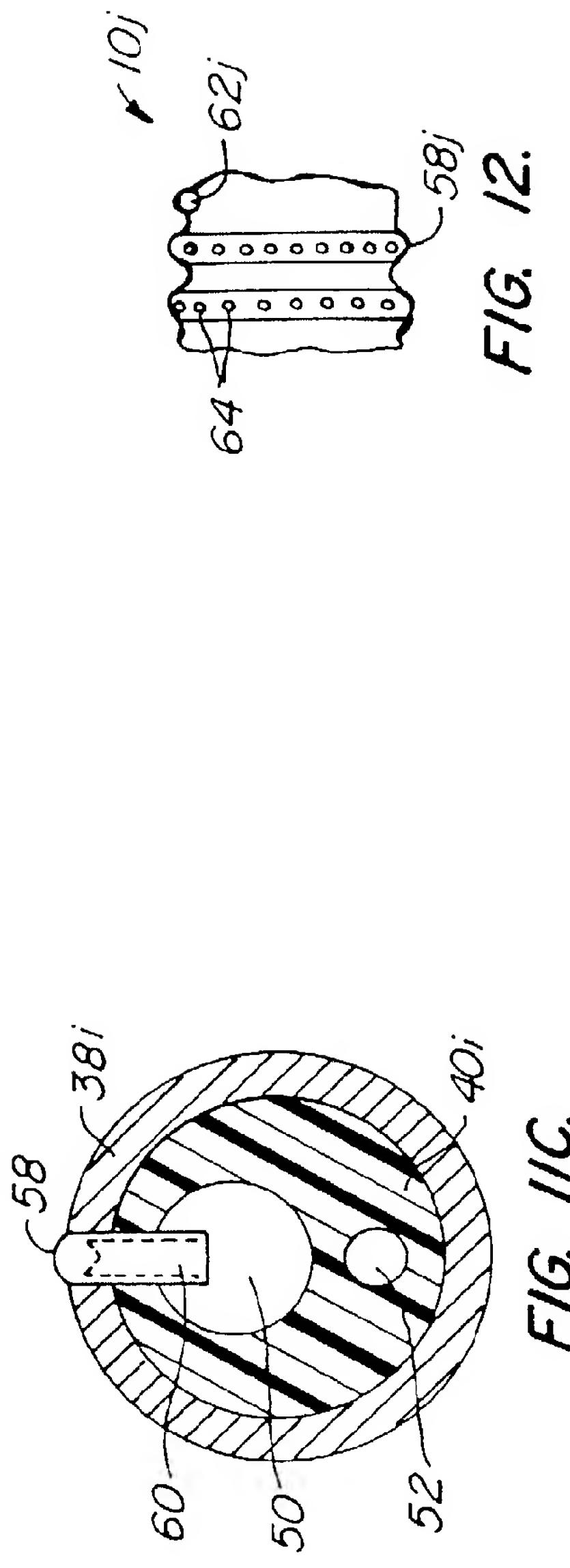
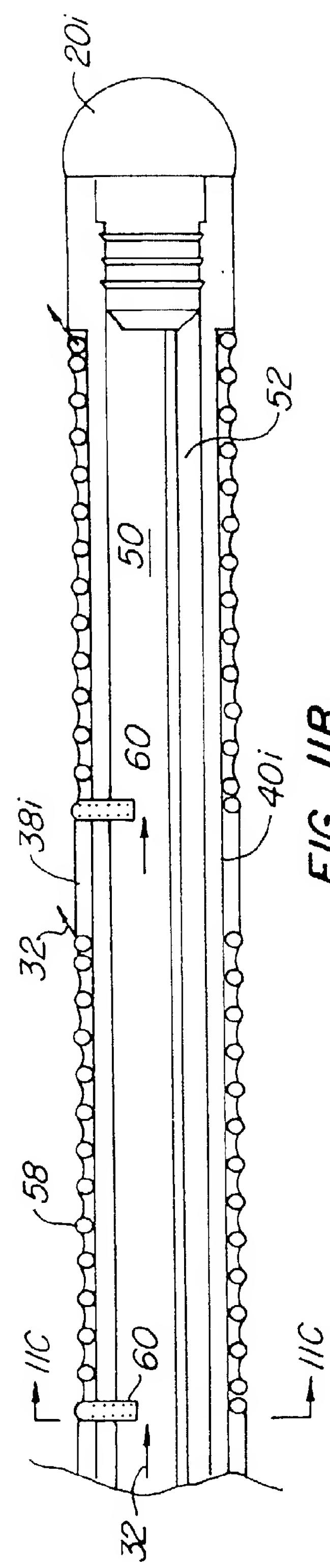
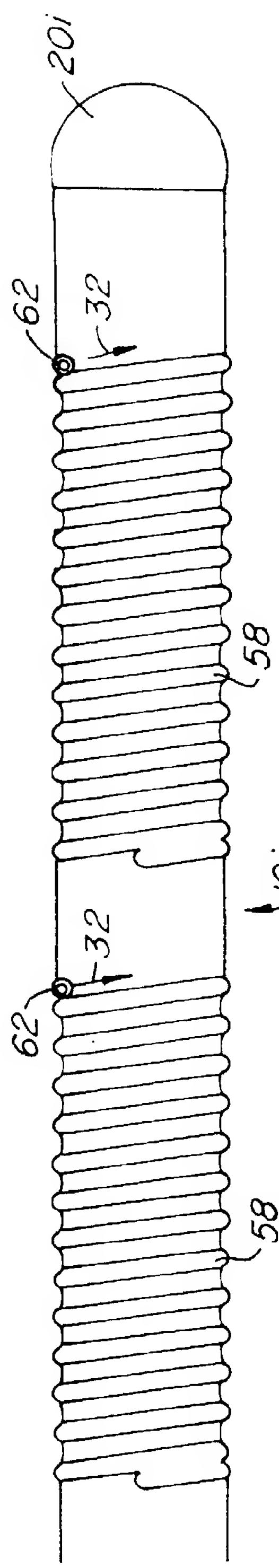


FIG. 11.





DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.6)						
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim							
A,D	US 5 462 521 A (BRUCKNER) 31 October 1995 * column 6, line 46 - column 2, line 21; figure 11 * ---	1,10,15, 16	A61B17/39						
A	WO 96 39966 A (WEBSTER) 19 December 1996 * abstract; figures 3,4 * ---	1,10,15, 16							
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<p>The present search report has been drawn up for all claims</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Place of search</td> <td style="width: 33%;">Date of completion of the search</td> <td style="width: 34%;">Examiner</td> </tr> <tr> <td>THE HAGUE</td> <td>10 June 1998</td> <td>Papone, F</td> </tr> </table>				Place of search	Date of completion of the search	Examiner	THE HAGUE	10 June 1998	Papone, F
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CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document							
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document									